

REMARKS

Claims 1-5, 7, 9, and 11-14 are pending in the instant application. Claims 1-4, 7, and 11-14 have been amended. No new claims have been added and no new matter is introduced by the amendments to the previously presented claims. The amendments to the claims and to the specification are formal in nature and support for each amendment can be found throughout the originally-filed specification and drawings.

Objections to the Claims

The Examiner has objected to the claims in connection with a number of informalities. As Applicants have amended the claims to conform with each of the Examiner's suggestions, Applicants believe the cited informalities have now been resolved. Accordingly, Applicants respectfully request withdrawal of the objections to the claims.

Objections to the Specification

The disclosure stands objected to as improperly including embedded hyperlinks or other browser-executable code. Applicants submit that amendments to the specification, presented above, renders this objection moot. In particular, Applicants note that the cited passages no longer include embedded hyperlinks or other browser-executable code. Accordingly, withdrawal of this objection is respectfully requested.

Claims Rejections

Rejection Under 35 U.S.C. § 112, second paragraph

Claims 13 and 14 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite in their recitations of "the T-DNA." In particular, the Examiner contends that there is

insufficient antecedent basis for that limitation in the claim. Claim 14 stands rejected as depending from a rejected claim. As outlined in the amendment to Claim 13, presented above, Applicants have removed the recitation of “the T-DNA” from the Claim. Accordingly, Applicants submit that the rejection has been rendered moot and withdrawal is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-5, 7, 9, and 11-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez *et al.*, WO 98/38323, (hereinafter “Perez *et al.*”) in view of Dellaporta *et al.*, Plenum Press, 263-282 (1998) (hereinafter “Dellaporta *et al.*”), Ishida *et al.*, Nature Biotechnology, 14(6):745-750 (1996) (hereinafter “Ishida *et al.*”), and Yoshida *et al.*, Journal of Bioscience and Bioengineering, 90:353-362 (2000) (hereinafter “Yoshida *et al.*”).

In making the instant rejection the Examiner relies primarily on the teachings of Perez *et al.* as outlining the claimed method. In particular, the Examiner contends that Perez *et al.* teaches a method of obtaining a transgenic maize plant containing a coding sequence of interest, such as the AMS gene coding for male sterility, that is free of ancillary sequences. The Examiner supplements this teaching with the remainder of the cited art to argue the application of the general methods disclosed in Perez *et al.* could be extended to: (1) the use of the Ac transposase of the R-nj::Ac allele of the R-nj chromosome as a phenotypic marker of excision (based on Dellaporta *et al.*); (2) the use of the maize line 188 (Ishida *et al.*); and (3) the incorporation of a selection using GFP (based on Yoshida *et al.*).

Although the Examiner suggests that Perez et al. teach a method of obtaining a transgenic maize plant free of ancillary sequence, Applicants respectfully submit, as discussed in detail below, that the methods disclosed in Perez et al. actually result in the retention of a fixed transposase sequence as well as an antibiotic resistance gene in the final transgenic maize plants. The retention of such genes during the process of generating transgenic maize is exactly the disadvantage of earlier processes that is addressed by the instant invention. As outlined at paragraph [0004] of the instant application, using such methods “[selectable marker genes] remain in the plant and, consequently, can also be detected in the form of DNA or of proteins in certain derived products, whereas generally they do not provide any added value to the transformed plant obtained. The presence of these genes, and in particular the genes for resistance to antibiotics and herbicides, is today at the center of numerous debates regarding genetically modified organisms (Flavell et al., 1992; Chesson et al., 2000).” It is this concern over the introduction of antibiotic resistance (or other functional marker) genes into the wild that has created the desire to seek out alternatives to the strategies disclosed in Perez et al., such as the currently claimed method.

In describing the general method outlined in Perez et al., the Examiner points out that Perez et al. begins by teaching the transformation of a first plant with a first T-DNA vector including the gene of interest followed by at least one selection sequence, such as nptII, and the appropriate regulatory sequences. Although the selection and regulatory sequences are flanked by mobilizable sequences responsive to a transposase, Perez et al. note that the gene of interest is inserted outside of the mobilizable sequences and will thus be retained even if the sequence intervening the mobilizable sequences is excised (as outlined in Figure 1 of Perez et al.).

The plant generated by this initial transformation is then crossed with a plant containing a transposase introduced into its genome using a second T-DNA vector (pBios144, which is described in detail in Figure 3). This second T-DNA vector is important in that it not only includes the left and right border T-DNA sequences necessary for introduction of the transposase into the second plant's genome, but it also includes a nptII antibiotic resistance gene and a "fixed" transposase.¹ It is this fixed transposase that allows for the final step of the process.

The final step of the method described by Perez et al. proceeds as follows:

- (1) The fixed transposase is expressed in a cell containing the transgenes provided both the first T-DNA vector and the second T-DNA vector;
- (2) The transposase introduced via the second T-DNA vector exerts its effects on the mobilizable sequences introduced via the first T-DNA vector;
- (3) The selection and regulatory sequences flanked by those mobilizable sequences are excised, but the gene of interest, which is not flanked by mobilizable sequences, is not excised.

Thus, the final step leaves the gene of interest without any associated ancillary sequence from that first T-DNA vector. However, as noted above, the transposase introduced by the second T-DNA vector is fixed and is incapable of excising itself. In addition, the nptII gene that was introduced along with the fixed transposase in the second T-DNA vector is also retained due to the lack of any mobilizable sequences flanking it. Accordingly, the method described in Perez et al. involves the retention of a significant amount of ancillary sequence, including the particularly problematic antibiotic resistance gene.

¹ A "fixed" transposase is one that is incapable of excising itself due to a mutation in one or both of its mobilizable sequences.

The U.S. Patent and Trademark Office (“PTO”) published new guidelines on October 10, 2007, for Examiners to use in performing an obviousness analysis based on the recent U.S. Supreme Court decision in *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). Fed. Reg. 72:195, 57526-57535 (Oct. 10, 2007). The new guidelines state that PTO personnel must make the underlying factual inquiries required by *Graham v. John Deere Co.*: (1) determine the scope and content of the prior art; (2) ascertain the differences between the claimed invention and the prior art; and (3) resolve the level of ordinary skill in the art. In addition, the PTO guidelines also set forth seven specific rationales for rejecting claims as obvious based upon those underlying factual inquiries as well as the specific requirements that must be met to support a rejection under each rationale.

The Examiner’s rationales for the instant rejections are that one of ordinary skill in the art would have been motivated by the art itself to combine various aspects of *Dellaporta et al.*, *Ishida et al.*, and *Yoshida et al.* to arrive at the instantly claimed invention. (See Pages 8-9 of the instant Office Action). In light of this language, the obviousness rejection appears to be based upon the rationale identified as “G. Some Teaching, Suggestion, or Motivation in the Prior Art That Would Have Led One of Ordinary Skill To Modify the Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention.” Fed. Reg. 72:195 at 57534. To support a rejection under this rationale, the guidelines note that it must be established that “one of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” *Id.* Furthermore, the guidelines state that “if any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.” *Id.*

Applicants respectfully submit that the references, alone or in combination, do not teach or suggest each and every feature of the pending claims, and therefore the suggested combination could not have “achieved the claimed invention” as required by the PTO’s own obviousness guidelines and the prevailing case law. *Id.*; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In particular, Applicants note that the method described by Perez et al. does not result in the removal of all ancillary sequence, due to the use of second T-DNA vector that introduces both a fixed transposase and an antibiotic resistance gene that is not flanked by mobilizable sequences . This retention of ancillary sequence would not be cured even if the proposed combination with Dellaporta et al. was permitted, as significant ancillary sequence necessary to the function of the method described in Perez et al. would be retained even if an active Ac element from a R-nj::AC allele of the R-nj chromosomal locus was used. Given these differences from the claimed invention, and the fact that neither Ishida et al. nor Yoshida et al. provide sufficient teaching to supplement the deficiency identified in Perez et al., Applicants respectfully request withdrawal of the instant rejection.

Conclusion

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. An early allowance is earnestly sought. To expedite allowance of this application, the Examiner is invited to telephone the undersigned if the Examiner believes a telephone call would be helpful in advancing prosecution.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Steve Lendaris', with a long horizontal flourish extending to the right.

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